Apex Knee System **December 20, 2007**

1. Submitter: OMNI life science™, Inc.
175 Paramount Drive
Raynham, MA 02767

Contact: Mr. William S. McCallum
Director of Regulatory and
Quality Systems
(508) 824-2444 (voice)
(508) 822-6030 (fax)

FEB 14

2. Device Name

Proprietary Name:	Apex Knee System Porous Coated Femoral Components
Common Name:	Total Knee Replacement Prosthesis
Classification Names:	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer Prosthesis, knee, patellofemorotibial, semi-constrained, uncemented, polymer/metal/polymer
Regulatory Classes:	Class II per 21 CFR §888.3560 Class II (special controls) per 21 CFR §888.3565
Product Codes:	JWH, MBH

3. Intended Use

The Apex Knee System is intended for use as a primary or revision total knee replacement. This knee replacement system is intended for cemented fixation, with the option of using a porous coated femoral component for uncemented or cemented fixation. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed.

4. Device Description

The Apex Knee System Porous Coated Femoral Components are part of the Apex Knee System for primary or revision total knee replacement. These cobalt chrome femoral components have a sintered porous coating (ASTM F1377). Fixation of the femoral component is achieved using either PMMA bone cement or by biological fixation via tissue ingrowth into the porous coating. The Apex Knee System consists of a range of sizes of femoral components with a deep patellar groove, dome shaped UHMWPE patella resurfacing components, UHMWPE tibial inserts, cobalt chrome tibial trays, and a titanium alloy bolt for locking the tibial insert to the tibial tray. This modular configuration allows the surgeon user to choose a combination of femoral and tibial tray component sizes to appropriately fit the anatomy of the patient, and to use a tibial insert with a size-for-size match to the femoral component. There are two different articular geometries for the tibial insert, a cruciate retaining ("CR") design, which allows retention of the posterior cruciate ligament, and an ultra-congruent posterior cruciate substituting ("Ultra") design. For each tibial insert, a range of UHMWPE thicknesses are available to aid in obtaining the proper soft tissue balance across the knee joint.

5. Predicate Device Comparison

Substantial equivalence is claimed to the Apex Knee System (K060192), distributed by OMNI life science, Inc., and the Sigma Cruciate-Retaining Porocoat® Femoral Components distributed by DePuy Orthopedics (K062654). The following table summarizes the similarities and differences between the subject uncemented femoral components of the Apex Knee System and these predicate devices:

	Apex Knee Porous Coated Femoral Components	**Apex Knee Cemented Femoral Components (K060192)**	**Sigma* Porocoat® Femoral Components (K062654)**
INTENDED USE			
Primary and revision, 3 compartment	Yes, cemented or uncemented	Yes, cemented	Yes, cemented or uncemented
DESIGN			
Porous coated	Yes	No	Yes
Asymmetric femur, anatomic patella groove	Yes	Yes	Yes
Anatomic (asymmetric) tibial tray	Yes	Yes	No
Metal-backed UHMWPE tibial component	Yes	Yes	Yes
Tibial insert designs	CR and Ultra	CR and Ultra	CR ("Curved")
Tibial tray distal features	Central post and 2 keels	Central post and 2 ~~short~~ keels	Central post and 2 ~~short~~ keels
Patella design	Round, single radius dome, 3 pegs	Round, single radius dome, 3 pegs	Round, single radius dome, 3 pegs
MATERIALS			
Femoral component	Cobalt chrome	Cobalt chrome	Cobalt chrome
Femoral porous coating	Yes, sintered cobalt chrome	No	Yes, sintered cobalt chrome

The only change to the Sponsor's predicate Apex Knee System (K060192) is the addition of a sintered cobalt chrome porous coating to the femoral components. This porous coating is similar to the sintered cobalt chrome porous coating on the predicate DePuy femoral components, and has the same bead configuration (sizes and shapes) as the Sponsor's Apex Modular Acetabular Cup (K031110). All other materials, designs, and manufacturing, packaging, and sterilization methods are identical to the predicate Apex Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

OMNI life science, Inc.
% Mr. William McCallum
Director, Regulatory and Quality
175 Paramount Drive, Suite 302
Raynham, Massachusetts 02767

Re: K073602
Trade/Device Name: Apex Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, MBH
Dated: January 25, 2008
Received: January 28, 2008

Dear Mr. McCallum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073602

Device Name: OMNI life science Apex Knee System

Indications For Use:

The Apex Knee System is intended for use as a primary or revision total knee replacement. This knee replacement system is intended for cemented fixation, with the option of using a porous coated femoral component for uncemented or cemented fixation. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed.

Prescription Use__X____ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073602